

LOPERAMIDE HYDROCHLORIDE - loperamide hydrochloride solution

Roxane Laboratories, Inc

RX ONLY

CONSUMER INFORMATION ON USES, DIRECTIONS AND WARNINGS FOR LOPERAMIDE HYDROCHLORIDE ORAL SOLUTION. PLEASE SAVE THIS FOR FUTURE REFERENCE.

ANTIDIARRHEAL

Loperamide hydrochloride oral solution relieves diarrhea for adults and children 6 years and older, often in just one dose. Loperamide hydrochloride has been recommended for millions of people, and has been proven to be an exceptionally safe and effective antidiarrheal medication.

INDICATION

Loperamide hydrochloride oral solution controls the symptoms of diarrhea, including Travelers' Diarrhea.

DIRECTIONS

Use the enclosed dosage cup to accurately measure loperamide hydrochloride as noted below. Drink plenty of clear fluids to help prevent dehydration, which may accompany diarrhea.

ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER

Take 4 teaspoonfuls (20 mL) after the first loose bowel movement and 2 teaspoonfuls (10 mL) after each subsequent loose bowel movement but no more than 8 teaspoonfuls (40 mL) a day for no more than 2 days.

CHILDREN 9-11 YEARS OLD (60-95 LBS)

Take 2 teaspoonfuls (10 mL) after the first loose bowel movement and 1 teaspoonful (5 mL) after each subsequent loose bowel movement but no more than 6 teaspoonfuls (30 mL) a day for no more than 2 days.

CHILDREN 6-8 YEARS OLD (48-59 LBS)

Take 2 teaspoonfuls (10 mL) after the first loose bowel movement and 1 teaspoonful (5 mL) after each subsequent loose bowel movement but no more than 4 teaspoonfuls (20 mL) a day for no more than 2 days.

Children under 6 years old (up to 47 lbs): Consult a physician. Not intended for use in children under 6 years old.

WARNINGS

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. Do not use for more than two days unless directed by a physician. **DO NOT USE IF DIARRHEA IS ACCOMPANIED BY HIGH FEVER (GREATER THAN 101°F), OR IF BLOOD OR MUCUS IS PRESENT IN THE STOOL, OR IF YOU HAVE HAD A RASH OR OTHER ALLERGIC REACTION TO LOPERAMIDE HYDROCHLORIDE.** If you are taking antibiotics or have a history of liver disease, consult a physician before using this product. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. In case of accidental overdose, seek professional assistance or contact a poison control center immediately. Store at Room Temperature 15°-30°C (59°-86°F).

ACTIVE INGREDIENT

Loperamide Hydrochloride 1 mg per teaspoonful (5 mL). Alcohol and sugar free.

Inactive Ingredients: flavor, glycerin, methylparaben, propylene glycol, propylparaben, sodium saccharin, and water.

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PACKAGE LABEL - LOPERAMIDE HYDROCHLORIDE ORAL SOLUTION

NDC 0054-8534-16 - 1 mg/5 mL - Antidiarrheal

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NDC 0054-8535-16 - 2 mg/10 mL - Anitdiarrheal
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